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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,794	03/20/2006	Terrence C. Dahl		7159

25000 7590 10/31/2007

GILEAD SCIENCES INC
333 LAKESIDE DR
FOSTER CITY, CA 94404

EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,794	DAHL ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *59,61,62,64,66,67,70-73,75,77-88,96,98-101,103-109,111,113-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/20/07
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 59,61,62,64,66,67,70-73,75,77-88,96,98-101,103-109,111 and 113-125.

DETAILED ACTION

Applicant's arguments filed 8/20/07 have been fully considered but they are not persuasive. See argument below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims *59,61,62,64,66,67,70-73,75,77-88,96,98-101,103-109,111,113-125* are rejected under 35 U.S.C. 103(a) as being unpatentable over Liotta et al (WO 92/14743; 09/03/92), Becker et al (WO 02/08241 A2; 01/31/02), and Fiske et al (Pharmcokinetics, safety and tolerability of single escalating doses of DMP 266, an HIV non-nucleoside reverse transcriptase inhibitor, in healthy volunteers, Pharmaceutical Research (New York), 1997, vol. 14 no. 11 Suppl. Pp. S609. print.). Liotta teaches a method of treating HIV by administering emtricitabine to a patient infected with HIV. See abstract and claims. Liotta teaches that emtricitabine can be combined with ingredients such as magnesium stearate, corn starch, carriers, and other antiviral compounds prior to administration. See page 52. Liotta also teaches that the composition can exist in the form of a tablet or capsule. Liotta does not teach a method of treating an HIV infected patient comprising administering a composition comprising tenofovir disoproxil fumarate (PMPA) and Sustiva to the patient. Liotta also does not teach the instant amounts or ratios of actives and instruction information on how to administer the drugs. However,

Becker teaches a method of treating an HIV infected patient comprising administering a tenofovir (PMPA) compound including tenofovir disoproxil to the patient. See abstract and claims. Likewise, Fiske teaches a method of administering sustiva (DMP 266) to treat an HIV infected patient. It would have been obvious to one having ordinary skill in the art to add both tenofovir disoproxil fumarate and sustiva to the tablet or capsule containing emtricitabine. One would have been motivated to do this because Liotta encourages the addition of other antiviral compounds to emtricitabine. One having ordinary skill at the time the invention was made would have been expected to determine the optimum amounts or ratios of ingredients to include in the dosage form. One would have been motivated to do this in order to optimize the effectiveness and safety of the dosage form. With respect to instructions on how to use pharmaceuticals, including the one of the instant claims, it is a standard practice to provide a patient consuming the product with instructions on how to administer or use the product in order to arrive at a patient pack or kit. Note the combination of the references cited in this rejection would yield an invention consisting of emtricitabine, disoproxil fumarate and optionally sustiva as the active ingredients. Applicant provides no unexpected or synergistic results for the drug combination.

Response to Applicants' argument

Applicants argue:

1) The disclosure on pages 50-51 relating to tablets and other dosage forms appear to be standard disclosure in Liotta et al. Liotta et al do suggest including "nucleoside" compounds. However, TDF would

not be properly considered a nucleoside because it does not contain the 5' hydroxymethyl terminus. Liotta et al's disclosure of antiviral compounds is too general to have instructive meaning.

2) Liotta et al teach that any chemical or compound to be included in the emtricitabine (FTC) dosage forms should not be expected to impair the FTC activity. Tenofovir disoproxil fumarate (TDF) would impair the desired antiviral effect FTC. The combination of TDF and FTC would result in a substantial prospect of reciprocal catalytic degradation of TDF and FTC. Therefore, it would not have been obvious to co-formulate TDF and FTC to arrive at a stable combination of TDF and FTC which has been founded by the Applicants.

3) Applicant found the optimal amounts of excipient substantially improve the storage stability of the combined tablets.

The Examiner argues:

1) Liotta et al do disclose that FTC tablets can comprise other antiviral agents. While Liotta et al do not disclose specifically that TDF is added to the tablets, TDF is known to be an antiviral agent. Therefore, in absence of unexpected results, it would have been obvious to include TDF in the FTC containing tablets. Note, a reference does not have to specifically layout the ingredients being combined in order to render a combination of ingredients obvious.

2) The claims are to a method of treating HIV not to the stability of the combination of antiviral drugs combined which Applicants appear to argue. Therefore while the Applicants may have found a way to make a stable combination of the claimed antiviral drugs, Applicants do not make claim to such an invention. It appears from the disclosure of Liotta et al reference that it would have been obvious to combine the antiviral agents to use in a method of treating HIV as instantly claimed.

3) Applicants do not provide any data or literature attesting to the difficulty of co-formulating TDF with FTC and that the addition of TDF to FTC would impair the activity of FTC which appears to be the basis of their argument.

For the above reasons the 35 USC 103(a) rejection on record is maintained over Liotta et al, Becker et al and Fiske et al.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alton Pryor
Primary Examiner
AU 1616